

### **REMARKS**

Applicants have received and carefully reviewed the Office Action of the Examiner mailed April 21, 2009. Currently, claims 1-2, 4-7, 9-11, 33 and 35-38 remain pending. Claims 1-2, 4-7, 9-11, 33 and 35-38 have been rejected. Favorable consideration of the following remarks is respectfully requested.

#### ***Claim Rejections under 35 U.S.C. § 103***

On page 2 of the Office Action, claims 1, 2, 4-7, 9-11, 33 and 35-38 were rejected under 35 U.S.C. §103(a) as being anticipated by Engelson (U.S. Patent No. 5,095,915) in view of Dobak, III et al. (U.S. Patent No. 6,096,068). After careful review, Applicants respectfully traverse this rejection.

Turning to claim 1, which recites:

1. A medical device, comprising:
  - an elongate core member having a longitudinal axis, wherein the core member includes a solid cross-sectional portion having a solid, non-hollow cross-section taken perpendicular to the longitudinal axis;
  - a polymer jacket affixed to at least a portion of the solid cross-sectional portion of the core member, the polymer jacket having a textured outer surface having a first diameter; and
  - wherein the textured outer surface includes a helical groove having a second diameter, less than the first diameter, formed in the outer surface of the polymer jacket, the helical groove defined by one or more rounded edges extending between the first diameter of the outer surface and the second diameter of the helical groove.

In the Office Action, the Examiner acknowledges that Engelson fails to disclose the helical groove has rounded edges, but turns to Dobak, III et al. for support. Applicants respectfully assert that the Dobak, III et al. reference is non-analogous art to the present application.

As the Examiner is aware, a *prima facie* case of obviousness is established "when the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art." *Application of Rinehart*, 531 F.2d 1048, 1052 (CCPA, 1976). "The reference must either be in the field of the applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned" *In re Oetiker*, 977 F.2d 1443, 1447 (Fed. Cir. 1992). In *Application of Wood*, the court presumes, when determining obviousness, "full knowledge by the inventor of all the prior art in the field of

his endeavor. However, with regard to prior art outside the field of his endeavor, we only presume knowledge from those arts reasonably pertinent to the particular problem with which the inventor was involved." 599 F.2d 1032, 1036 (CCPA, 1979).

For example, in *Wang v. Toshiba Corp.*, a reference was nonanalogous where patent claims were directed to single in-line memory modules (SIMMs) for installation on a printed circuit motherboard for use in personal computers, and the reference was directed to a SIMM for an industrial controller. 993 F.2d 858 (Fed. Cir. 1993). The court determined that the reference was not necessarily in the same field of endeavor as the claimed subject matter merely because it related to memories (emphasis added). *Id.* The reference was found to be in a different field of endeavor because it involved memory circuits in which modules of varying sizes may be added or replaced, whereas the claimed invention involved compact modular memories. *Id.*

Furthermore, single memory modules of the claims at issue were intended for personal computers and used dynamic random-access-memories, whereas reference SIMM was developed for use in large industrial machine controllers and only taught the use of static random-access-memories or read-only-memories. *Id.*

In another example, *In re Oetiker*, the court held the reference was not within the field of applicant's endeavor, and was not reasonably pertinent to the particular problem with which the inventor was concerned because it had not been shown that a person of ordinary skill, seeking to solve a problem of fastening a hose clamp, would reasonably be expected or motivated to look to fasteners for garments that was taught in the reference, even though the Board reasoned that all hooking problems are analogous. 977 F.2d 1443 (Fed. Cir. 1992).

The Field of the Invention of Dobak, III et al. broadly discloses that it "relates generally to modification and control of the temperature of a selected body organ." (Column 1, lines 18-19). The field of the invention is further defined and supported throughout the application and referred to as a "heat transfer device". In contrast, the field of Applicants' endeavor, reflected in the present application, is to some extent reflected in the "Field of Invention" portion of the application and is the following: "medical devices including guidewires...more particularly...to guidewires with a helically contoured portion". Similar to the example cases cited above, Dobak, III et al. is not in Applicants' field of endeavor merely because it relates to medical devices.

Additionally, the Dobak, III et al. reference is not reasonably pertinent to the particular

problem with which the inventor was concerned. Just as in *In re Oetiker*, where fasteners for garments was not reasonably pertinent to the problem of fastening a hose clamp even though they both involved a "hooking problem", here heat transfer devices for modifying and controlling the temperature of an organ, that is taught in Dobak, III et al. is not reasonably pertinent to the current application, despite Dobak, III et al. teaching "articulated segments". The parts are entirely different and not "reasonably pertinent" to each other. As such, the Dobak, III et al. reference is not in the field of Applicants' endeavor or reasonably pertinent to the particular problem with which the inventor was concerned and, hence, is non-analogous art.

Further, even if the Dobak, III et al. reference is considered analogous art (which Applicants believe is not), Applicants respectfully assert that Engelson and Dobak, III et al. are not combinable as asserted by the Examiner. Engelson discloses a guidewire 36 including an elongate wire core 38 having a distal end section encased in an elongate polymeric sleeve 44. A helical groove 46 can be formed in the sleeve 44 by cutting with a blade. (See column 4, lines 57-61). In contrast, Dobak, III et al. disclose a heat transfer element 14 comprised of a series of articulating segments or modules. As can be seen in Figure 5 of Dobak III, et al., a working fluid may be circulated through the heat transfer element 14. Fluid flows up a supply catheter into an insulated inner coaxial lumen 40. At the distal end of the heat transfer element 14, the working fluid exits the inner coaxial lumen 40 and enters an outer lumen 46. Nothing in Dobak, III et al. discloses how to form one or more rounded edges in an elongate polymeric sleeve 44, as taught by Engelson. Further, one of skill in the art would not replace the elongate polymeric sleeve 44 of Engelson with the articulating segments of Dobak, III et al. that provide for a flow of a fluid therein. Therefore, there is no reason to combine the teaching of Engelson with the teaching of Dobak, III et al. to arrive at the claimed invention.

Even if Engelson and Dobak, III et al. may be combinable in the manner suggested by the Examiner, it is axiomatic that "because they can be" clearly fails to establish a proper *prima facie* case of obviousness. Under KSR, there must be some reason to make the claimed combination. The Supreme Court in *KSR Int'l Co. v. Teleflex Inc.* quotes *In re Kahn*, 441 F. 3d 977, 988 (CA Fed. 2006) stated:

"[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness".

(Emphasis added) (see page 14 of the April 30, 2007 decision). The Court further stated:

a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.

(see page 14 of the April 30, 2007 decision). It appears that the Examiner has merely found several elements of the claim in the prior art and has made a conclusion of obviousness without any articulated reasoning with some rational underpinning to support the conclusion. Applicants submit that the only motivation or reason for combining Engelson and Dobak, III et al. in the manner suggested by the Examiner comes from Applicants' own specification, which is clearly improper. Therefore, for at least these reasons, claim 1 is believed to be patentable over Engelson and Dobak, III et al. For similar reasons and others, claims 2 and 4-5, which depend from claim 1 and which include additional distinguishing features, are believed to be patentable over Engelson and Dobak, III et al.

For similar reasons and others, independent claims 6, 33, and 35 are believed to be patentable over Engelson and Dobak, III et al. For similar reasons and others, claim 7, 9-11, and 36-38, which depend from one of claims 6 and 35 and which include additional distinguishing features, are also believed to be patentable over Engelson and Dobak III, et al.

### **Conclusion**

In view of the foregoing, all pending claims are believed to be in a condition for allowance. Further examination and withdrawal of the rejections is respectfully requested. Issuance of a Notice of Allowance in due course is anticipated. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,  
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By their Attorney,

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